DIRC Newsletter

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Official Desk

Pharmacy Inspector

It's my pleasure to share with you all that the Karnataka State Pharmacy Council is appointing Pharmacy Inspectors for the State as per section 26(A) of the Pharmacy Act, 1948.

The Pharmacy Inspectors duty is to visit the Pharmacy outlets across Karnataka to ascertain the physical presence of the Registered Pharmacist and to document the same in the inspection form provided by the Council.

Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council

Pharmacy Inspectors have to inform the Pharmacist to renew their Registration every year to avoid removal of name from the register of Karnataka State Pharmacy Council.

The salient features of the appointment and the job description of the Pharmacy inspectors will be displayed on our Council website shortly.

Scholarship Scheme

As mentioned in official desk of the Jan-March 2018 DIRC Newsletter, the Council has already launched 'Scholarship Scheme for the legal heirs of the Registered Pharmacists of KSPC' who pursues Pharmacy education (D.Pharm, B.Pharm, M.Pharm, Pharm.D and Pharm.D (PB)).

The main objective of the scheme is only to financially support the legal heirs (son/daughter) of Registered Pharmacists who pursue the Pharmacy education. The prior criterion is the renewal status of Registered Pharmacist must be up to date / current.

The eligible applicants will get the benefit of the Scheme.

Renewal

The renewal of Registration for the period 2019 will be opened from 1st December 2018. The Registered Pharmacist can avail this service through our website and mobile app.

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FELICITATION

Sri. Gangadhar V. Yavagal, President, Sri.D.A.Gundu Rao, Vice President and Prof.B.G.Shivananda, Registrar of Karnataka State Pharmacy Council felicitated Dr.B.Suresh who was elected for the fourth consecutive term as the president of the Pharmacy Council of India at JSS Academy of Higher Education & Research, Mysuru.

Dear Registered Pharmacists,

The Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT) has increased the welfare trust benefit from Rs.1,00,000/- to Rs.1,25,000/-. If you have not enrolled for KPCRPWT and below 60 years, you can apply through online. For more information refer general instructions of KPCRPWT-A. Ignore if already enrolled / applied.

Managing Trustee
KPCRPWT

World Pharmacists Day 2018: Your Medicines Experts

Dr. R. S. Thakur
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World Pharmacists Day 2018 will be celebrated throughout the world on 25th September. "Pharmacists are Your Medicines Experts" is the theme of this year's World Pharmacists Day. It highlights the role of Pharmacist in the society and their strenuous efforts in keeping people healthy.

The hospital and community Pharmacists play a very important role in protecting and improving public's health. They use their extensive expertise on medicines every day to ensure better patient health through accurate dispensing of prescriptions and unambiguous dissemination of instructions for use and application of medicines by the patient or patient's attendant. It must be emphasized that while dispensing a prescription Pharmacists ensure that right medicine, in right dose and right dosage form, is administered to the right patient through right route, at right time so as to avoid any untoward effect and achieve maximum therapeutic benefit. Safe, effective, and economic (low cost best quality) medication are focus of pharmaceutical care. Thus for every patient, pharmacists ensure rational therapy and adequate counseling by applying the principles of pharmacotherapeutics, pharmacoeconomics and pharmacovigilance.

Dispensing and handing over medicines to patients are not the only tasks performed by pharmacists. Drug information, storage and preservation of potency/quality of medicines and expert clinical opinion of pharmacists are equally important for rationale and economic therapy. Patients need counselling on anxiety and worries about their health problems and that works too.

Checking prescription by Pharmacists before dispensing medication to patients ensures that patients don't receive any wrong medicine or take an incorrect dose of medicine. A pharmacist instructs on how and when to use the medicines to avoid serious consequences for patients, up to and including death.

As Indian Health care set up is almost fully dependent upon western or modern allopathic medicines imported into India by British traders turned rulers, and that being the most preferred system of medicine in India, we must adopt western design of pharmaceutical care and services to protect mankind from menace of medicines. The huge gap between pharmaceutical services settings in western world and India is mounting alarming devastation on health and happiness of citizens. Medicine related deaths and disabilities are becoming common and the sole reason behind is out dated or primitive pharmaceutical care set up. If India is committed to use western allopathic medicines, its Pharmaceutical care network also must be on the same lines as prevailing in Europe or US. Any compromise is ruinous for public health, and that is worst thing for any republic.

Therefore, to meet the cherished goal of "Health for all" we must have Directorate of Pharmacy in the Health and Family Welfare Department to evolve Pharmaceutical Care Policy and deal with all matters related to drugs and pharmaceuticals, medicine's quality, manufacturing and availability of essential medicines at competitive cost, proper storage and preservation of potency of medicines, pharmacy education, and pharmaceutical industry promotion.

The Vision, Mission, Objectives and functions of the Directorate of Pharmacy along with its values are described below:

Vision: To be a provider of world class quality pharmaceutical care services to the citizens.

Mission: To provide within the available resources good quality medicines and medical supplies that are safe, effective, accessible, affordable and rationally used.

To ensure quality education for Pharmacists.

To create environment for vibrant entrepreneurial culture, and State-of-the-art manufacturing facilities for quality medicines and medical devices.

Objectives: To improve the health of people through proper procurement, promotion of local production of essential medicines and management of adequate supply of medicines ensuring: Accessibility, Affordability, Availability, Efficacy, Quality, Rational usage, and Safety.

Functions

(i) To avail essential medicines throughout the State, including 100% availability of all essential medicines at all times at all places.

(ii) Selection of medicines and medical supplies according to the Essential Medicines concept of the World Health Organisation (WHO) and National List of Essential Medicines 2015 (NLEM) in collaboration with Hospital Medicine and Therapeutics Committees (HMTCs) of the State.

(iii) Robust Quality assurance measures to ensure supply of safe, effective quality medicines and medical devices.

(iv) To promote cost effective production of medicines within the State in accordance with the standards of current Good Manufacturing Practices (cGMP).

(v) To procure and distribute safe and effective medicines of acceptable quality, in the necessary quantities, at the lowest possible cost, and to ensure that these medicines are maintained in good condition throughout the supply chain in order to minimize wastage and loss of potency.

(vi) To promote rational use of medicines, both through prescribing, and dispensing in the public and private sectors.

(vii) To establish Pharmacy Colleges for education and training of Pharmacists of all levels.

(viii) To promote research in the field of drugs, Pharmaceuticals, Phytochemicals, and Pharmaceutical Care for continuous development and improvement in all aspects of health sector.

(ix) To monitor the performance of each sector and derive parameters for continuous improvement in the system to meet world class requirements in every segment of Pharmacy Services.

Values

The Directorate of Pharmacy Services will be guided by the following values:

1. Accountability
2. Adaptability
3. Beneficiary and Health Care Provider Satisfaction
4. Equity
5. Excellence
6. Integrity
7. Professionalism
8. Transparency

On this World Pharmacists Day let us move closer to creating a healthy society and protect mankind from menace of medicines through rational therapy and Medication Therapy Management. ❑

Pharmacists: Your Medicines Experts

Mr. Katta Anand Srinivas
Registered pharmacist

On the occasion of World Pharmacist Day which was celebrated on September 25, I thought it would be apt to contribute an article highlighting the pharmacists role.

"Pharmacists: Your medicines experts" is the theme of this year's World Pharmacists Day which is celebrated on 25th September. "This year, we focus on the extensive expertise that pharmacists have and put to use every day, to ensure better patient health. Pharmacists are a trusted source of knowledge and advice, not only for patients but for other healthcare professionals.

Pharmacists are also called Chemist, Druggist, Apothecary and is a member of health care team directly involved with patient care. Pharmacists are patient oriented professionals who work towards meeting the health care requirements of their patients. They not only dispense medications but also give advice on side effects, drug interactions, use of medical devices and a lot of other aspects related to health care.

A Pharmacists goes through a gamut of questions in his everyday work. They can range from which medication to use for a rash, which is a preferred diabetic meter, demonstrating an asthmatic patient as to how to use an inhaler. An elderly gentleman who came to pick up his blood thinner medication wanted to know which foods he need to avoid when he is on this medication and a teenager required insights from the pharmacist on which acne cream she needs to use. There was also a concerned mother of a 2-year-old boy who needed recommendation of which medication she can use for her son's diarrhea and vomiting.

Learning when to take a medication: Can you drink alcohol when you are on an antibiotic, when should I start my new birth control medicine, your pharmacist will have the answer.

Managing side effects: Is the medication for treatment of your triglycerides causing a flush, is your blood pressure medications causing a dry cough, is the medications for your mood causing a reduction in sexual desire, your pharmacist will provide alternatives which you can discuss with your doctor.

List all your other medicines or supplements: Are you taking Calcium or iron products, they can decrease the bioavailability of your antibiotic ciprofloxacin or your thyroid medication, garlic supplements can interact with your blood-clot medications. It is better to give the details of all medications and supplements which you take to your pharmacist so that he can advise you accordingly.

Birds eye view your pharmacist can review the list of medications you take to find out if there are any major drug-drug interaction and alert you and in turn your physician for making necessary changes in the drug regimen.

Questions you need to ask your pharmacist

1. What's the name of the medicine and what is it for?
2. How and when do I take it and for how long?
3. What side effects should I expect, and what should I do about them?
4. Should I take this medicine on an empty stomach or with food?
5. Should I avoid any activities, foods, drinks, alcohol or other medicines while taking this prescription?
6. If it's a once-a-day dose, is it best to take it in the morning or at night?
7. Will this medicine work safely with my other medications, including other prescription medicines, over-the-counter medicines, vitamins and other supplements?
8. When should I expect the medicine to begin to work and how will I know if it's working?
9. How should I store it?
10. Is there any additional information I should know about this medicine?

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Drug of the Quarter

Drug: **Vortioxetine**

Class: Antidepressant

Dosage form: Film coated tablet

Strength: 5mg/10 mg/15mg/20mg

DCGI Approval: 14-05-2018

USFDA Approval: 30-09-2013

Indication: Treatment of major depressive disorder in adults

Dose Information

Adult Dosing:

The recommended starting dose is 10 mg administered orally once daily without regard to meals. Dosage should then be increased to 20 mg/day, as tolerated. Dosage may be reduced to 5 mg/day for intolerance.

Pediatric Dosing: Safety and efficacy not established in pediatric patients.

Pharmacokinetics

Absorption

- Tmax, Oral: 7 to 11 hours
- Effects of food: None

Distribution

- Protein binding: 98%
- Vd: 2600 L

Metabolism

- Extensively metabolized by oxidation via CYP2D6
- Carboxylic acid metabolite: inactive

Excretion

- Fecal: 26%, as metabolites
- Renal: 59%, as metabolites

Elimination Half Life: 66 hours

Contraindication:

- Concomitant use with an MAOI (use within 14 days of discontinuing an MAOI used to treat psychiatric disorders or MAOI use within 21 days after vortioxetine discontinuation), including linezolid or IV methylene blue; increased risk of serotonin syndrome.

Caution:

- **Endocrine and metabolic:** Increased risk of hyponatremia, which may be the result of SIADH, has been reported with serotonergic drugs, in patients who are elderly, receiving concomitant diuretics or patients who are otherwise volume depleted.
- **Hematologic:** Increased risk of bleeding events, including life-threatening hemorrhages, has been reported with SSRIs, with concomitant use of NSAIDs, aspirin, warfarin and other anticoagulants.
- **Hepatic:** Use not recommended in patients with severe hepatic impairment.
- **Neurologic:** Increased risk Serotonin syndrome, potentially life-threatening, has been reported with concomitant use of serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St John's wort) and drugs that impair metabolism of serotonin (eg, MAOIs, including methylene blue IV and linezolid). Monitoring recommended and discontinue if suspected.
- **Ophthalmic:** Angle closure attack may occur in patients with anatomically narrow angles without an iridectomy.
- **Psychiatric:** Activation of mania or hypomania may occur. Use cautiously in patients with personal or family history of bipolar disorder, mania, or hypomania.
- **Psychiatric:** Manic or mixed episodes may be precipitated by use of antidepressants alone in patients at risk for bipolar disorder. Caution.

Storage & Stability

Store at a controlled room temperature of 25 degrees C (77 degrees F); excursions permitted between 15 and 30 degrees C (59 and 86 degrees F).

Mechanism of Action: Vortioxetine is a serotonergic antidepressant that inhibits the reuptake of serotonin (5-HT), antagonizes 5-HT3, 5-HT1D and 5-HT7 receptors, agonizes 5-HT1A receptors and is a partial agonist of the 5-HT1B receptor.

Adverse Effects

Common

- Gastrointestinal: Constipation, Nausea, Vomiting

Serious

- Endocrine metabolic: Hyponatremia
- Hematologic: Hemorrhage, Abnormal
- Psychiatric: Hypomania, Mania, Suicidal thoughts
- Other: Serotonin syndrome

Drug-Drug Interactions

Category	Drug/s (Examples	Interaction Effect	Management
Antibiotic*	Linezolid	May result in increased Vortioxetine exposure and thereby increases the risk of serotonin syndrome (hypertension, hyperthermia, myoclonus, mental status changes).	Contraindicated for concurrent use.
Monoamine Oxidase Inhibitors*	Isocarboxazid, Phenelzine, Selegiline	May result in increased Vortioxetine exposure and thereby increases the risk of serotonin syndrome (hypertension, hyperthermia, myoclonus, mental status changes).	Contraindicated for concurrent use.
Anticoagulants**	Heparin, Warfarin, Dipyridamole, Phenindione, Enoxaparin, Acenocoumarol	May result in an increased risk of bleeding.	Avoid concomitant use.
Strong CYP2D6 inhibitors**	Quinidine, Bupropion, Abiraterone Acetate	May result in increased Vortioxetine exposure.	Avoid concomitant use.
Strong CYP Inducers**	Phenytoin, Primidone, Dexamethasone, Rifampin, Rifabutin, Enzalutamide	May result in decreased Vortioxetine exposure	Avoid concomitant use.
Antidepressant**	Paroxetine	May result in increased Vortioxetine exposure and thereby increases the risk of serotonin syndrome (hypertension, hyperthermia, myoclonus, mental status changes).	Use with caution.
Antidepressant**	Fluoxetine	May result in decreased Vortioxetine exposure.	Use with caution.
Anticonvulsant**	Carbamazepine	May result in decreased Vortioxetine exposure.	Use with caution.

Severity: *The drugs are contraindicated for concurrent use.
**The interaction may be life-threatening and/or require medical intervention to minimize or prevent serious adverse effects.

Effects in Pregnancy

Severity	Management
Moderate	No USFDA rating is available for Vortioxetine. Available evidence is inconclusive or is inadequate for determining fetal risk when used in pregnant women or women of childbearing potential. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy.

Effects in lactation

Severity	Management
Major	Infant risk cannot be ruled out. Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when Vortioxetine is used during breast-feeding. Weigh the potential benefits of treatment against potential risks before prescribing Vortioxetine during breast-feeding.

Patient Education:

1. Please advise the patient or caretaker to report worsening of depression, suicidal ideation, agitation, irritability or unusual changes in behavior, especially at initiation of therapy or with dose changes.
2. Advise the patient to report symptoms of mania or hypomania, abnormal bleeding or hyponatremia.
3. Advise the patient not to discontinue this drug without the advice of the doctor.

References:

1. http://www.micromedexsolutions.com/
2. http://www.cdsco.nic.in/
3. http://www.rxlist.com/

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Drug Safety Alerts - National

Pharmacovigilance Programme of India (PvPI)

The preliminary analysis of Serious Unexpected Serious Adverse Reaction (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below.

Sl. No.	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported
			April 2018	
1.	Dexamethasone	Corticosteroid	Adjunct in the emergency treatment of anaphylaxis; short term suppression of inflammation in allergic disorders; adrenocortical insufficiency, ocular inflammation, autoimmune disorders, rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics.	Peripheral Neuropathy
			March 2018	
2.	Cefixime	Antibiotic-3rd Generation Cephalosporin	For treatment of Otitis media, respiratory tract infections, uncomplicated UTIs, effective against infections caused by enterobacteriaceae, H. Influenza species.	Skin Hyperpigmentation
			February 2018	
3.	Dapsone	Anti-infective	For treatment of leprosy; acne vulgaris, dermatitis, pneumocystic pneumonia.	Erythema nodosum
			January 2018	
4.	Levetiracetam	Anti-epileptic drug/ Anticonvulsant	For treatment of myoclonus-generalised epilepsy with photosensitivity, idiopathic epilepsy of generalised tonic clonic seizures, post-encephalitic myoclonic epilepsy; encephalopathies; severe myoclonic epilepsy, absence seizure.	Hypokalaemia

Healthcare professionals, Patients / Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs.

If such events are encountered, please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

Reference: www.ipc.gov.in

Meanings: Encephalopathy- a broad term used to describe abnormal brain function or brain structure, **Peripheral neuropathy-** damage to the peripheral nerves, **Erythema nodosum-** A painful disorder characterized by tender bumps (nodules) under the skin.

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Serious Risks/Safety Information – USFDA

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) - USFDA

The USFDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

The appearance of a drug on this list does not mean that conclusive of the risk. It means that FDA has identified a potential safety issue, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines whether the drug is associated with the risk or not and it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS) or gathering additional data to better characterize the risk.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Dosage Form	Potential Signal of a Serious Risk / New Safety Information	Additional Information
January – March 2018					
Bronchodilators	Albuterol Sulfate, Ipratropium Bromide and Albuterol, Levalbuterol Tartrate	Inhalation	Inhalation solution, Inhalation spray, Inhalation aerosol, Inhalation powder, for oral Inhalation use	Albuterol sulfate and serious skin reactions.	FDA decided that no action is necessary at this time based on available information.
Antirheumatic/ Immunological agent	Tocilizumab, Rilonacept, Canakinumab, Sarilumab, Anakinra	Intravenous	Injection	IL-1 and IL-6 inhibitors and pulmonary hypertension, interstitial lung disease, pulmonary alveolar proteinosis.	Evaluation is in progress.
Cardiovascular agent	Riociguat	Oral	Tablet	Syncope	FDA decided that no action is necessary at this time based on available information.
CNS agent / hypnotic	Zolpidem Tartrate, Eszopiclone, Zaleplon	Oral	Tablet, Capsule	Somnambulism or Abnormal Sleep-related event	Evaluation is in progress.
Antineoplastic agent	Bosutinib, Imatinib, Mesylate, Ponatinib, Dasatinib, Nilotinib	Oral	Tablet, Capsules	Thrombotic microangiopathy	Evaluation is in progress.
Antidote/ Central Nervous System Agent	Sugammadex	Intravenous	Injection	Laryngospasm Bronchospasm	Evaluation is in progress.
Nutritive Agent	Levocarnitine	Intravenous, Oral, Solution	Injection, Tablet, Oral Solution	Hypersensitivity and anaphylaxis	The labeling section of the product was updated to include hypersensitivity reactions.
Diagnostic Agent/ Gastrointestinal Agent	Sincalide	Intravenous	Injection	Anaphylaxis, anaphylactic shock and other hypersensitivity reactions	The labeling section of the product was updated to include anaphylaxis and hypersensitivity reactions.
Anticonvulsant	Lamotrigine	Oral	Tablet	Hemophagocytic lymphohistocytosis (HLH)	The labeling section of the product was updated to include hemophagocytic lymphohistocytosis.
Antifungal	Posaconazole, Itraconazole	Oral, Intravenous, Suspension	Delayed-release tablets, injection, oral suspension, capsules	Excess Mineralocorticoid	Evaluation is in progress.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Dosage Form	Potential Signal of a Serious Risk / New Safety Information	Additional Information
Antithyroid drug	Propylthiouracil	Oral	Tablet	Fatal cases of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis.	Evaluation is in progress.
Antiemetic	Rolapitant	Oral, Intravenous	Tablet, Injectable emulsion for intravenous use	Infusion related and hypersensitivity reactions	Evaluation is in progress.
October - December 2017					
Cardiovascular Agent/ Sclerosing agent	Polidocanol, Sodium Tetradecyl Sulfate	Intravenous	Injection	Cardiovascular adverse events like arterial embolism.	The labeling section of the product was updated to include arterial embolism.
Antiulcer	Misoprostol	Oral	Tablet	High fevers (greater than 104 degrees Fahrenheit or 40 degrees Celsius)	The labeling section of the product was updated to include high fevers greater than 104 degrees Fahrenheit or 40 degrees Celsius.
Antiemetic	Fosaprepitant	Intravenous	Injection	Infusion site reactions	Evaluation is in progress.
Antibiotic/ Anti-Infective Agent	Erythromycin lactobionate	Intravenous	Injection	Drug interaction with HMG-CoA reductase inhibitors (lovastatin and simvastatin) extensively metabolized by CYP3A4 (enzyme) resulting in myopathy and rhabdomyolysis	Evaluation is in progress.
Antidiabetic	Metformin Hydrochloride	Oral, Solution	Tablet, Oral Solution	Serious skin reactions	Evaluation is in progress.
Anticonvulsant	Lamotrigine	Oral	Tablet	Labetalol-lamotrigine name confusion/medication errors associated with serious outcomes	FDA decided that no action is necessary at this time based on available information.
Adenosine Receptor Agonist	Regadenoson	Intravenous	Injection	Serious cardiac adverse events following prolonged Lexiscan administration (>10 seconds)	Evaluation is in progress.
Antiasthma/ Anti-Inflammatory	Montelukast sodium	Intravenous	Tablet	Neuropsychiatric adverse reaction	Evaluation is in progress.
Antidiabetic	Dapagliflozin, Empagliflozin, linagliptin, Canagliflozin, Canagliflozin and Metformin Hcl, Empagliflozin, Dapagliflozin and Saxagliptin, Empagliflozin and Metformin Hydrochloride, Dapagliflozin and Metformin Hcl	Oral	Tablet	Fournier's gangrene	Evaluation is in progress.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Dosage Form	Potential Signal of a Serious Risk / New Safety Information	Additional Information
Antidiarrheal/ Gastrointestinal Agent	Eluxadoline	Oral	Tablet	Anaphylaxis and hypersensitivity	The labeling section of the product was updated to include hypersensitivity or serious allergic reactions.

References:

1. http://www.fda.gov/
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2018, Truven Health Analytics Inc.

Meanings: **Rhabdomyolysis-** A breakdown of muscle tissue that releases a damaging protein into the blood. Somnambulism- Sleepwalking, **Thrombotic Microangiopathy-** A pathology that results in thrombosis in capillaries and arterioles, due to an endothelial injury, **Hemophagocytic Lymphohistocytosis-** An uncommon hematologic disorder seen more often in children than in adults, **Fournier's gangrene-** A rare and often fulminant necrotizing fasciitis of the perineum and genital region frequently due to a synergistic polymicrobial infection. ❑

Drug News – Around the Globe

1. Drug: Ribociclib* **Country: USA**

Ribociclib is an antineoplastic drug.

Approved Indication: Ribociclib in combination with an aromatase inhibitor is approved for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. Warnings include the risk of a heart problem known as QT prolongation that can cause an abnormal heartbeat and may lead to death, serious liver problems, low white blood cell counts that may result in infections that may be severe, and fetal harm.

Approved Dosage Form: Injection

Side-effects: Infections, abnormally low count of a type of white blood cell (neutropenia), a reduction in the number of white cells in the blood (leukopenia), headache, cough, nausea, fatigue, diarrhea, vomiting, constipation, hair loss and rash[1].

2. Drug: Tecovirimat* **Country: USA**

Tecovirimat is an antiviral drug.

Approved Indication: Tecovirimat is the first drug approved for treatment of smallpox caused by variola virus. It is administered orally within 30 minutes of a full moderate- to high-fat meal.

Approved Dosage Form: Oral

Side-effects: Headache, nausea and abdominal pain[1].

3. Drug: Lofexidine hydrochloride * **Country: USA**

Lofexidine hydrochloride is an Alpha-2 Adrenergic Agonist

Approved Indication: Lofexidine hydrochloride injection is approved for the mitigation of withdrawal symptoms and to facilitate abrupt discontinuation of opioids in adult patientss.

While Lofexidine may lessen the severity of withdrawal symptoms, it may not completely prevent them and is only approved for treatment for up to 14 days. This drug is not a treatment for opioid use disorder (OUD), but can be used as part of a broader, long-term treatment plan for managing OUD.

The safety and efficacy of Lofexidine have not been established in children or adolescents below 17 years of age.

Approved Dosage Form: Injection

Side-effects: Hypotension, bradycardia (slow heart rate), somnolence (sleepiness), sedation and dizziness.

4. Drug: Tofacitinib* **Country: USA**

Tofacitinib is an Alpha-2 Adrenergic Agonist

Approved Indication: The USFDA expanded the approval of Tofacitinib to treat adults with moderately to severely active ulcerative colitis. Previously it was approved for Rheumatoid arthritis.

Tofacitinib is the first oral medication approved for chronic use in this indication.

Approved Dosage Form: Oral.

Side-effects: Upper respiratory infection, nasopharyngitis, diarrhea or headache.

5. Drug: Pegvaliase-pqpz* **Country: USA**

Pegvaliase-pqpz is a pegylated derivative of the enzyme phenylalanine ammonia-lyase that metabolizes phenylalanine to reduce its blood levels.

Approved Indication: Pegvaliase-pqpz was approved for adults with a rare and serious genetic disease known as phenylketonuria (PKU)

Approved Dosage Form: Subcutaneous injection

Side-effects: Injection site reactions, joint pain, hypersensitivity reactions, headache, generalized skin reactions.

6. Drug: Erenumab-aooe* **Country: USA**

Erenumab-aooe is an Anti-migraine drug.

Approved Indication: Erenumab-aooe is indicated in adults for the preventive treatment of migraine. The treatment is given by once-monthly self-injections. Erenumab-aooe is the first FDA-approved preventive migraine treatment in a new class of drugs that work by blocking the activity of calcitonin gene-related peptide, a molecule that is involved in migraine attacks.

Approved Dosage Form: Subcutaneous injection

Side-effects: Injection site reactions and constipation.

7. Drug: Migalastat* **Country: USA**

Migalastat is an Endocrine-Metabolic Agent

Approved Indication: Migalastat is approved as the first oral medicine for the treatment of adults with Fabry disease.

Approved Dosage Form: Oral

Side-effects: Headache, nasal and throat irritation (nasopharyngitis), urinary tract infection, nausea and fever.

Reference:

1. www.fda.gov

Meaning: Fabry disease- An inherited disorder that results from the buildup of a particular type of fat, in the body›s cells.

Note - * Not available in India

Safety Alerts – Around the Globe

1. Drug: Lamotrigine* **Country: USA**

May cause severe inflammation throughout the body

Lamotrigine is used alone or with other medicines to treat seizures in patients two years and older. It may also be used as maintenance treatment in patients with bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania.

Alert: The USFDA has warned that Lamotrigine can cause a rare but very serious reaction that excessively activates the body's infection-fighting immune system. This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. The symptoms may vary from patient to patient like fever and rash, enlarged spleen, cytopenias, elevated levels of triglycerides or low blood levels of fibrinogen, high levels of blood ferritin, hemophagocytosis identified through bone marrow, spleen, or lymph node biopsy, decreased or absent Natural Killer (NK) cell activity, elevated blood levels of CD25 showing prolonged immune cell

Hence, KSPC-DIRC alerts the healthcare professionals to be cautious while prescribing Lamotrigine[1].

2. Drug: Erythropoietins* **Country: Singapore**

May increase the risk of severe cutaneous adverse reactions (SCAR)

Recombinant Human Erythropoietins (r-HuEPOs) are a class of biologics generally used for the treatment of anaemia associated with chronic renal failure.

Alert: The Health Sciences Authority (HAS) of the Singapore Ministry of Health has alerted that severe cutaneous adverse reactions (SCAR) including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported overseas in patients treated with recombinant human erythropoietins. There were 23 reports of SJS and 14 reports of TEN with r-HuEPOs were identified. Among them, a causal association was found for eight reports of SJS and one case of TEN.

Hence, KSPC-DIRC alerts the healthcare professionals to educate their patients on the early recognition of signs and symptoms of allergic reactions and the importance of prompt withdrawal of r-HuEPOs if signs and symptoms are presented [2,3].

3. Drug: Hyoscine butylbromide* **Country: New Zealand**

May increase the risk of cardiovascular adverse reactions

Hyoscine butylbromide is used to treat muscle spasm in the gastrointestinal tract.

Alert: The New Zealand Medicines and Medical Devices Safety Authority issued an alert warning that use of hyoscine butylbromide injection can lead to cardiovascular adverse reactions, such as hypotension and tachycardia. Internationally, there are fatal reports of patients who received intravenous or intramuscular injection of hyoscine butylbromide. There were nine reports of suspected cardiovascular adverse reactions to hyoscine butylbromide injection between 2013 and 2017 in New Zealand alone.

Hence, KSPC-DIRC alerts the healthcare professionals that hyoscine butylbromide injection should be used with caution in patients with underlying cardiovascular disease[4].

4. Drug: Obeticholic acid** **Country: Ireland**

May increase the risk of serious liver injury.

Obeticholic acid is indicated to treat primary biliary cholangitis.

Alert: The Health Products Regulatory Authority (HPRA) of Ireland has alerted that the patients with pre-existing moderate or severe liver impairment who are taking obeticholic acid are at risk of serious liver injury and adequate dose reduction in these patients is therefore essential.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety changes for Obeticholic acid [5].

5. Drug: Dolutegravir** **Country: USA, Europe**

May cause potential risk of neural tube birth defects

Dolutegravir is an antiretroviral medicine used in combination with other antiretroviral medicines to treat human immunodeficiency virus (HIV).

Alert: The USFDA has alerted that serious neural tube birth defects involving the brain, spine and spinal cord in babies born to women has been reported for those patients treated for human immunodeficiency virus (HIV) with dolutegravir.

The USFDA recommends that the patients should not discontinue taking dolutegravir without talking to their respective Physician as discontinuing the medicine can cause the HIV infection to worsen. Hence the women of childbearing age should be informed about the potential risk of neural tube defects.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety alerts for dolutegravir[1].

6. Drug: Sodium-glucose cotransporter-2 (SGLT2) inhibitors* **Country: USA**

May cause Fournier's gangrene

Sodium-glucose cotransporter-2 (SGLT2) inhibitors like canagliflozin, dapagliflozin, empagliflozin, ertugliflozin are indicated for type 2 diabetes mellitus.

Alert: The U.S. Food and Drug Administration (FDA) is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called Sodium-glucose cotransporter-2 inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene.

Hence, KSPC-DIRC alerts the healthcare professionals about the new safety alerts for the drugs belonging to class of sodium-glucose cotransporter-2 inhibitors [1].

References:

1. www.fda.gov.in/
2. WHO Pharmaceuticals Newsletters No.1, 2018: Risk of Severe Cutaneous Adverse Reactions (SCARs) in Ireland and in UK.
3. Health Sciences Authority (HSA), Singapore. http://www.hsa.gov.sg/
4. Prescriber Update, Medsafe, June 2018 (www.medsafe.govt.nz/).
5. Drug Safety Newsletter, HPRA, June 2018 (www.hpra.ie).
6. Product Safety Alerts, HSA, 11 May 2018 (http://www.hsa.gov.sg/).

Notes - *Available in India ** Not available in India

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Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Psoriasis-Drug Therapy- Continuation from the previous newsletter issue

(Topical & Oral)

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Pimecrolimus **Route:** Topical	Treats atopic dermatitis, which is a form of eczema.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or if patient have other skin problems or a weak immune system.	Mild burning, warmth, itching or soreness, runny or stuffy nose, cough, sore throat.	Advise patient to apply this topical medicine to the affected skin areas only and to avoid drug exposure to eyes, nose, mouth or broken skin. Advise patient to limit sun exposure and to avoid sun lamps and tanning beds. Advise the patient not to use this drug for long-term until unless advised by the doctor.
Tacrolimus **Route**: Topical/Oral	Treats atopic dermatitis (a skin rash and type of eczema), prevents body from rejecting an organ after transplant.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding, or having kidney disease, liver disease, diabetes, heart disease, heart rhythm problems, high blood pressure, or any type of infection.	Diarrhea, constipation, nausea, vomiting, loss of appetite, upset stomach, trouble sleeping, acne, mild burning, stinging, tingling, redness, or itching when the medicine is applied, extra sensitive skin, headache, mild fever, swollen or infected hair follicles.	Advise to avoid alcohol. Advise to avoid grapefruit products. Advise the patient to take a missed oral dose as soon as possible after the scheduled dose.
Methoxsalen **Route:** Topical/Oral	Treats the symptoms of psoriasis.	Prescription to be reconfirmed in case of patient is pregnant or breast feeding or if any type of skin cancer or have liver diseases or any heart problems.	Nausea, trouble sleeping, unusual sadness or nervousness, blistering of your skin, mild skin rash.	Advise to avoid direct and indirect sun exposure for at least 8hrs after drug administration. Advise the patient against concurrent use of other photosensitizing agents, unless supervised by healthcare professional. Advise to take a missed dose as soon as possible.
Coal tar **Route:** Topical	Used to relieve drying, itching, flaking, scaling or irritation of the skin caused by psoriasis or seborrheic dermatitis.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have a skin problem that involves a large area of the body.	Burning, itching, swelling, or redness in the treated skin area	Avoid cosmetics or skin care products on the treated skin. Advise to wear sunscreen and not to use sunlamps or tanning beds as this medicine may make the skin more sensitive to sunlight.

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Cyclosporine **Route:** Oral	Treats rheumatoid arthritis, psoriasis, chronic dry eye, used as an immunosuppressant in organ transplantation.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding, have kidney disease, liver disease, cancer, anemia, a bleeding disorder, high blood pressure, eye or vision problems or a history of seizures. Strictly advise to avoid alcohol.	Diarrhea, stomach pain, increased hair growth, swelling of your gums.	Advise to take at the same time every day with / without food. Advise to wear sunscreen and not to use sunlamps or tanning beds as this medicine may make the skin more sensitive to sunlight. Advise to discuss with doctor before stopping this medicine.
Azathioprine **Route:** Oral	Used for preventing renal transplant rejection. Also used for treating concomitant psoriasis and bullous pemphigoid.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding, have liver or kidney disease, shingles, an infection, or gout. Make sure the doctor knows that patient is taking allopurinol, cotrimoxazole, mercaptopurine, mesalamine, olsalazine, ribavirin, sulfasalazine, a blood thinner (such as warfarin), or certain blood pressure medicines (ACE inhibitors).	Hair loss, joint or muscle pain, sores or white patches on your lips, mouth, or throat.	Advise to take drug with food or in divided doses to decrease gastrointestinal intolerance. Advise to report any unusual bleeding or bruising and to report signs / symptoms of infection. Advise to consult the doctor prior to taking other new drugs including over-the-counter and herbal drugs as there are multiple significant drug-drug interactions for this drug.
Leflunomide **Route:** Oral	Treatment of rheumatoid arthritis and psoriatic arthritis and psoriasis.	Prescription to be reconfirmed in case of patient is pregnant, have kidney disease, liver disease, diabetes, any infection, lung disease or a history of tuberculosis or blood or bone marrow problems.	Diarrhea, hair loss.	Advise to avoid pregnancy during therapy and before completion of the drug elimination procedure. Advise to avoid live vaccines during therapy.

Storage: Advice the patient or caretaker to store the medicine in a closed container at room temperature, away from heat, moisture and direct light. Ensure to keep all medicine out of the reach of children.

References:

1. Handbook of Pharma SOS, Educational Series-I, 7th Edition 2018, published by Karnataka State Pharmacy Council, Bangalore.
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2018, Truven Health Analytics Inc.
3. https://www.webmd.com/
4. http://emedicine.medscape.com/

Drug Usage in Special Population - Pediatrics and Geriatrics

(From KSPCDIRC publication)

Anti-infectives / Antibiotics

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Anthelmintics		
Albendazole	Safety and efficacy have not been established in peadiatric patients below 2 years of age.	Dosage adjustment may not be required. Renal elimination is minimal.
Mebendazole	Safety and efficacy have not been established in peadiatric patients below 2 years of age.	Dosage adjustment may not be required in renal impairment but required in liver impairment.
Antifilarials		
Diethylcarbamazine	Safety and efficacy have not been established in peadiatric patients.	Dosage adjustment may be required in renal impairment especially those with an alkaline urine (eg, pH 8).
Antibacterial Drugs		
Amikacin Sulphate	Dosage adjustment required in pediatric patients with renal insufficiency.	No dosage adjustment required. But caution in case of renal impairment.

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Amoxycillin	Dosage adjustment may be required in pediatric patients with severe renal impairment.	Dosage adjustment may be required in severe renal impairment.
Amoxycillin + Clavulanic Acid	Dosage adjustment may be required in mild, moderate and severe renal failure. Caution in patients with hepatic impairment.	Dosage adjustment may be required in mild, moderate and severe renal failure.
Ampicillin	Dosage adjustment required in severe renal impairment.	Dosage adjustment required in severe renal impairment.
Azithromycin	Safety and efficacy have been well established in pediatric patients above 6 months old.	Dosage has to be adjusted. Caution in patients with impaired liver, renal and prolonged QT interval.
Benzyl Penicillin	Caution in case of penicillin allergy individuals, impaired renal function and seizure disorder.	Dosage adjustment required in renal impairment. Initial renal function has to be checked before starting the therapy.
Cefazolin	Dosage adjustment required in pediatric patients with mild to moderate renal impairment.	Dosage reduction advised in renal failure. Adjustment not required in patient with hypothyroid condition.
Cefotaxime	Dosage adjustment is required in-patients with hepatic insufficiency with concurrent renal failure. Dosage has to be halved in renal failure. No dosage adjustment required in hepatic impairment.	Dosage adjustment is required in patients with hepatic insufficiency with concurrent renal failure. Dosage has to be halved in renal failure. No dosage adjustment required in hepatic impairment.
Ceftazidime	Dosing interval adjustment should be made in case of renal impairment inconsistent with adult recommendation. No dosage adjustment required in hepatic impairment.	Dosage adjustment may be required in mild, moderate and severe renal failure.
Ceftriaxone	Dosage adjustment required if there is renal impairment with concurrent hepatic insufficiency or vice versa.	Dosage adjustment not required. Renal impairment: no dose adjustment needed hepatic impairment: no dose adjustment needed combined renal and hepatic impairment: doses should not exceed 2 g/day.
Cephalexin	No dosage adjustment required.	Dosage and duration adjustment required in renal impairment and in dialysis.
Chloramphenicol	No dosage adjustments of chloramphenicol are necessary during peritoneal dialysis in patients with jaundice.	Dosage adjustment required in case of renal and hepatic impairment.
Ciprofloxacin Hydrochloride	Safety and efficacy have not been established in peadiatric patients.	No dosage adjustment required. Renal function has to be monitored and if required dosage has to adjusted.
Cotrimoxazole (Trimethoprim + Sulphamethoxazole)	Not recommended in infants less than 2 months age. Dosage adjustment is required in renal impairment. Contraindicated in G6PD deficiency.	Dosage adjustment may be required due to reduced clearance of sulfonamides. No dosage adjustment required.

Reference: Drug Usage in special Population-Pediatrics and Geriatrics, Educational Series-II, 7thEdition 2018, published by Karnataka State Pharmacy Council, Bengaluru.

Drug Usage in Special Population - Pregnancy and Lactation

(From KSPCDIRC publication)

Anti-infectives / Antibiotics

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Anthelmintics		
Albendazole	USFDA Category C. Animal studies reveal that it may be teratogenic and embryotoxic at maternal toxic doses. Limited human data available. Use with caution.	Excretes in breast milk. Poor oral absorption by mother and probably by the infant. Use with caution.
Mebendazole	USFDA Category C. Toxicity in animal studies. No adequate human data but suggested possible association with limb reduction defects in first trimester exposure.	Excretes in breast milk. But this drug is minimally absorbed from GI tract. Use with caution.
Anti-filariasis		
Diethylcarbamazine	Risk classification not available. Treatment of pregnant patients with diethylcarbamazine should be delayed until after delivery. However, diethylcarbamazine has not been shown to cause birth defects or other problems in humans.	Unknown excretion into human breast milk. Use with caution.

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Antibacterial Drugs		
Amikacin	USFDA Category D. Limited data available. Due to reports of fetal ototoxicity (including deafness) with other aminoglycosides, use of this drug is not recommended.	Not known whether amikacin is excreted into human breast milk. Use with caution.
Amoxycillin	USFDA Category B. No case reports of congenital malformations or well-controlled studies of teratogenic effects, nor has teratogenicity been established in animal studies. Penicillins are relatively safe to use in pregnancy.	Safe to use.
Amoxycillin + Clavulanic Acid	USFDA Category B. Relatively safe to use in pregnancy.	Safe to use. But use with caution if antibiotic of choice and observe infant for adverse effects, particularly diarrhoea and thrush.
Azithromycin	USFDA Category B. Limited data available. Use only if adequate alternatives not available.	Excreted and accumulates in milk. But poses minimal risk to the infant.
Benzyl Penicillin (Penicillin G)	USFDA Category B. Not known to be harmful. Penicillin's are relatively safe to use in pregnancy.	Excreted into breast milk in negligible amounts. Safe to use in normal dose.
Cefditoren pivoxil	USFDA Category B. No human data available. Studies reveal that not teratogenic in animals.	No reports describing the excretion of drug in milk. However, use of this drug poses minimal risk to the infant.
Cefotaxime	USFDA Category B. Relatively safe to use in pregnancy.	Safe to use.
Ceftazidime	USFDA Category B. Relatively safe to use in pregnancy.	Excreted in low concentrations. Safe to use.
Ceftriaxone	USFDA Category B. Relatively safe to use in pregnancy.	Safe to use.
Cefazolin	USFDA Category B. No adequate human data available and no fetal adverse effects have been reported. Relatively safe to use in pregnancy.	Excreted into breast milk in low concentrations. Safe to use.
Cephalexin	USFDA Category B. Safe to use. No congenital malformations or fetal damage have been reported in women who received this drug.	Excreted in low concentrations. Safe to use.
Chloramphenicol	ADEC Category A. Limited data available. Report of neonatal grey syndrome in third trimester. Caution advised while use.	Not safe to use. Use alternative drug if possible, may cause idiosyncratic bone-marrow toxicity in infant.
Ciprofloxacin	USFDA Category C. Animal studies reveal that it causes teratogenic effects like arthropathy. Limited human data available. Fluoroquinolones are relatively contraindicated in pregnancy. Use only if potential benefits versus risk, since safer alternatives are usually available.	Controversial data. Use with caution.
Colistimethate	USFDA category C. Human data not available. This drug should be given only if the potential benefit justifies the potential risk to the fetus.	No reports describing the excretion of drug in milk.
Cotrimoxazole (Sulphamethoxazole + Trimethoprim)	USFDA Category C. Trimethoprim can cause folic acid deficiency in the fetus causing congenital anomalies. In third trimester, neonatal haemolysis and methaemoglobinaemia have been reported. Also possibility of kernicterus in the neonates. Caution advised while use.	Reports of small risk of kernicterus in jaundiced infants and of hemolysis in G6PD deficient infants (due to sulfamethoxazole). Monitor infant for jaundice. Caution in ill or premature infants.

USFDA Category B: Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

USFDA Category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans. Drug should be given only if the potential benefit justifies the potential risk to the fetus.

USFDA Category D: There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

ADEC Category A: Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Reference: Drug Usage in special Population-Pregnancy and Lactation, Educational Series-I, 7th Edition 2018, published by Karnataka State Pharmacy Council, Bangalore.

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ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015 (Pharmacy Practice Regulation, 2015)

ಅಧ್ಯಾಯ–1

2. ವ್ಯಾಖ್ಯಾನಗಳು:

(ಎ) "ಕಾಯ್ದೆ" ಎಂದರೆ, ಭೇಷಜೀ ಕಾಯ್ದೆ 1948 (1948 ರ 8ನೇ ಯದ್ದು)

(ಬಿ) ಭೇಷಜೀ ಪರಿಕರ್ಮ ಎಂದರೆ:–

(1) ವೈದ್ಯಕೀಯ ಆದೇಶಗಳನ್ನು ಅರ್ಥೈಸುವುದು, ಮೌಲ್ಯಮಾಪನ ಮಾಡುವುದು ಮತ್ತು ಅನುಷ್ಠಾನಗೊಳಿಸುವುದು; ವೈದ್ಯಲಿಖಿತಗಳನ್ನು ಮತ್ತು ಔಷಧಿ ಆದೇಶಗಳನ್ನು ವಿನಿಯೋಗಗೊಳಿಸುವುದು.

(2) ಔಷಧಿ ಮತ್ತು ಉಪಕರಣದ ಆಯ್ಕೆ ಪ್ರಕ್ರಿಯೆಯಲ್ಲಿ, ಔಷಧ ಉಣಿಸುವಲ್ಲಿ, ಔಷಧ ಸರಣಿಯ ಪುನರ್ವಿಮರ್ಶೆಗಳಲ್ಲಿ ಮತ್ತು ಔಷಧ ಅಥವಾ ಔಷಧಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಸಂಶೋಧನೆಗಳಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆ.

(3) ರೋಗಿ ಸಮಾಲೋಚನೆ ಒದಗಿಸುವುದು ಮತ್ತು ಪ್ರಾಥಮಿಕ ಆರೈಕೆ ಸೇರಿದಂತೆ, ರೋಗಿ ಪಾಲನೆಯ ಎಲ್ಲಾ ಆಯಾಮಗಳಲ್ಲೂ ಬೈಷಜ್ಯೀಯ ಆರೈಕೆ ಒದಗಿಸಲು ಅಗತ್ಯವೆನಿಸಿದ ಅಂತಹ ಕ್ರಿಯೆಗಳನ್ನು ಮತ್ತು ಸೇವೆಗಳನ್ನು ಒದಗಿಸುವುದು; ಮತ್ತು

(4) ಔಷಧಗಳನ್ನು ಮತ್ತು ಉಪಕರಣಗಳನ್ನು ಸಂಯುಕ್ತಗೊಳಿಸುವ ಮತ್ತು ಧಾರಕ ಹಚ್ಚುವ ಜವಾಬ್ದಾರಿ ವಹಿಸುವುದು (ವೈದ್ಯಲಿಖಿತ ಅನವಶ್ಯಕವಾದ ಔಷಧಿಗಳ ಮತ್ತು ವಾಣಿಜ್ಯಕವಾಗಿ ಪೊಟ್ಟಣಗೊಳಿಸಿದ ಸಾಂಪ್ರದಾಯಿಕ ಔಷಧಿಗಳಿಗೆ ಮತ್ತು ಉಪಕರಣಗಳಿಗೆ ಒಬ್ಬ ತಯಾರಕರಿಂದ, ಪುನರ್ ಪೊಟ್ಟಣಕಾರರಿಂದ ಅಥವಾ ವಿತರಕರಿಂದ ಧಾರಕ ಹಚ್ಚುವ ಪ್ರಕ್ರಿಯೆ ಹೊರತುಪಡಿಸಿ) ಔಷಧಿಗಳ ಮತ್ತು ಉಪಕರಣಗಳ ಸರಿಯಾದ ಹಾಗೂ ಸುರಕ್ಷಿತ ದಾಸ್ತಾನು ಜವಾಬ್ದಾರಿ ಮತ್ತು ಅವುಗಳಿಗೆ ಕ್ರಮಬದ್ಧವಾದ ದಾಖಲೆಗಳ ಪರಿಪಾಲನಾ ಜವಾಬ್ದಾರಿಗಳು.

(ಸಿ) "ಸಂಯುಕ್ತಗೊಳಿಸುವುದು" (ಕಾಂಪೌಂಡಿಂಗ್) ಎಂದರೆ, ಒಂದು ಔಷಧ ಅಥವಾ ಉಪಕರಣವನ್ನು ಈ ಕೆಳಗೆ ನಮೂದಿಸಿದ ಸಂದರ್ಭಗಳಲ್ಲಿ ತಯಾರಿಸುವ ಕ್ರಿಯೆ, ಮಿಶ್ರಗೊಳಿಸುವ ಕ್ರಿಯೆ, ಸಂಯೋಜಿಸುವ ಕ್ರಿಯೆ, ಪೊಟ್ಟಣಗೊಳಿಸುವ ಕ್ರಿಯೆ ಅಥವಾ ಧಾರಕ ಹಚ್ಚುವ ಕ್ರಿಯೆಗಳು –

(1) ಒಬ್ಬ ವೈದ್ಯರ ವೈದ್ಯಲಿಖಿತ/ ಔಷಧಿ ಆದೇಶದ ಪರಿಣಾಮವಾಗಿ (ಅಥವಾ) ವೃತ್ತಿಪರ ಪರಿಕರ್ಮದ ಅನುಷ್ಠಾನದಲ್ಲಿ ಒಬ್ಬ ವೈದ್ಯ/ರೋಗಿ/ಭೇಷಜಜ್ಞರ ಸಂಬಂಧದ ಬುನಾದಿಯ ಮೇಲೆ ಮೊದಲ್ಗೊಂಡ ಕ್ರಿಯೆಗಳು.

ಅಥವಾ

(2) ಸಂಶೋಧನೆ, ತಯಾರಿಸುವುದು, ಬೋಧನೆ, ನೈದಾನಿಕ ಪರಿಕ್ಷಣೆ ಅಥವಾ ಔಷಧಿ ವಿಶ್ಲೇಷಣೆ ಮತ್ತು ಮಾರಾಟಕ್ಕಲ್ಲದ ಅಥವಾ ಉದ್ದೇಶಗಳ ಅನುಷಂಗಿಕ ಪರಿಣಾಮವಾಗಿ ನಡೆಸಬೇಕಾದ ಕ್ರಿಯೆಗಳು.

ಸೂಚನೆ: ವೈದ್ಯಲಿಖಿತಗಳನ್ನು ನಿರೀಕ್ಷಿಸಿ ಮತ್ತು ವೈದ್ಯಲಿಖಿತಗಳ ವಿನ್ಯಾಸಗಳ ಮಾದರಿಯ ಮೇಲೆ ಔಷಧಗಳನ್ನು ಅಥವಾ ಉಪಕರಣಗಳನ್ನು ಸಿದ್ಧಗೊಳಿಸುವುದು ಸಹಾ ಸಂಯುಕ್ತಗೊಳಿಸುವುದರ ವ್ಯಾಖ್ಯೆಯಲ್ಲಿ ಸೇರಿರುತ್ತದೆ.

(ಮುಂದುವರಿಯುವುದು....)

ATTENTION

Govt. of India (GOI) Prohibits 328 Fixed Dose Combinations

The Ministry of Health & Family Welfare, Government of India has prohibited 328 Fixed Dose Combination (FDCs) of drugs for human use under Section 26A of Drugs & Cosmetics Act,1940 (23 of 1940) for manufacture for sale, sale and distribution in the country through Gazette notifications nos. S.O.4379 (E) to S.O.4706 (E) dated on 07-09-2018 with immediate effect. This prohibition is based on the recommendations of Drugs Technical Advisory Board (DTAB) as there is no therapeutic justification for the ingredients contained in these 328 FDCs or and these FDCs may involve risk to human beings as mentioned in the notification.

The copy of this notification is available on the Central Drugs Standard Control Organization (CDSCO) website.

Reference: https://cdsco.gov.in/

KSPC News

World Pharmacist Day Celebrations

1. Ikon Pharmacy College, Bidadi

Sri.Gangadar V Yavagal, President, Karnataka State Pharmacy Council, Bengaluru was the Chief Guest and Sri. Samson P George, Dy. Registrar cum DIRC Pharmacist, Karnataka State Pharmacy Council was the speaker for the 'World Pharmacist Day' celebration held in Ikon Pharmacy College, Bidadi on 29th September 2018.

Sri.Gangadar V Yavagal highlighted on the theme of Pharmacist Day "Pharmacists: Your Medicines Experts". He expressed the scope of upcoming Pharmacists as Medicines Experts and the challenges the Pharmacist would face in the coming days if they are not going to promote their services to the patients.

Sri.Samson P George encouraged all the fellow pharmacists, pharmacy students to use World Pharmacist Day as an opportunity to actively encourage the other healthcare professionals as well as general public regarding the valuable role Pharmacists could play in bringing good health in the community.

The guest of honour was Sri. Sunil S Chiplunkar, Vice-President, Juggat Pharma Ltd. The meeting was presided by Mr.Chinnaraj S., Secretary, Ikon Pharmacy College and Dr.S.Rajasekaran, Principal, Ikon Pharmacy College. 150 students along with management and staff of the college were present.

2. PES College of Pharmacy, Bengaluru

Mr. Samson P George, Dy. Registrar and DIRC Pharmacist, Karnataka State Pharmacy Council was the guest speaker for the 'World Pharmacist Day' celebration held at PES College of Pharmacy, Bengaluru on 25th September 2018. He delivered a talk on the theme "Pharmacists: Your Medicines Experts". He highlighted the role of Pharmacist in healthcare, timelines in the field of Pharmacy Practice, reason for professional pharmacy services, Pharmacy Practice Regulations, 2015 etc.

Dr.R. Srinivasan, HOD of Pharmacy Practice, Prof.Dr.Lakshman K., Prof.& HOD of Pharmacogonosy and 70 students with other staffs were present for the celebration.

3. Shree Devi College of Pharmacy, Mangalore

Shree Devi College of Pharmacy Mangalore celebrated the "World Pharmacist Day" on 25-09-2018. Dr Jagadish V Kamath, Principal, Shree Devi College of Pharmacy and Executive Committee Member, Karnataka State Pharmacy Council briefed about the significance of World Pharmacist Day.

During this celebration, Mr Shridhar Achar, Senior Pharmacist who is the proprietor of Shree Medicals, Udupi was felicitated. Dr M. H. Shareef, Associate Professor, Dept. of Pathology, Yenapoya Medical College, Mangalore was the Chief guest. Mrs Maina S Shetty, Secretary, Shree Devi Education Trust and Dr Dilip Kumar, Principal, Shree Devi Institute of Technology also were present during the celebration. A blood donation camp was organized in association with Yenapoya Medical College hospital. About 100 volunteers both students and staff donated blood on this occasion.

4. RMES' College of Pharmacy, Kalaburagi

Rajiv Memorial Education Society's College (RMES) of Pharmacy, Kalaburagi celebrated 'World Pharmacist Day' based on the theme: 'Pharmacists your Medicines Experts' on 25th Sept 2018 at Khandal Village, Gulbarga district.

Dr. Kishore Singh Chatrapathi, Director, Rajiv Memorial Education Society's College of Pharmacy, Kalaburagi and Executive Committee Member, Karnataka State Pharmacy Council organized a speech on 'Safe Use of Medicines and Dengue awareness program' to the villagers and followed by plantation of trees at new RMES campus during this celebration.

A leadership training program was given to the staff and students by Sri.Vijay Singh Thakur and group V2 skill Development at Kalaburagi.

Pharmacy Professional Association Meet

The Karnataka State Pharmacy Council (KSPC) has organized a meeting of President, Vice-President and Secretaries of various Pharmacy Professional Association on 01-09-2018 at the boardroom of this Council.

Sri.Gangadhar V. Yavagal, President welcomed the various professional association representatives and briefed about the purpose of organizing this meet.

The representatives of various Professional associations like Karnataka Registered Pharmacist Association (KRPA), IPA- Karnataka, APTI-Karnataka, AAGCP, KSGPA, IPA-Peenya attended the meet.

A power point presentation was given about various activities of KSPC, DIRC and KPCRPWT by Mr.Samson P George, Deputy Registrar cum DI Pharmacist. The following points were highlighted during the meet like online system for Registration, Online Renewal, benefits of enrolling to KPCRPWT, scholarship scheme, mobile app, CPE, DIRC etc.

There was also a separate demo of Online Renewal system and its importance as per the Pharmacy Act and the KSPC rules and importance of Continuing Pharmacy Education program as per Pharmacy Practice Regulations, 2015.

Visits by Dignitaries

Dr.Raveendra, Registered Pharmacist, USA visited the Council to discuss the new activities initiated by our Council.

Sri. Gangadhar V Yavagal, President welcomed Dr. Raveendra and explained about the ongoing activities along with the upcoming projects planned for the professional improvement of the Registered Pharmacist.

Dr.Raveendra appreciated the activity and explained about the different professional responsibility of Pharmacist in USA in contrast with the Pharmacist in India.

KPCRPWT Compensation

The death compensation of Rs.1,25,000 (One Lakh twenty five thousand) was handed over to the nominee Smt. Vita Bai B Tolnoorkar mother of Sri.Nagaraj B Tolnoorkar, KSPC Reg. No. 29804 by Dr. Kishore Singh Chatrapathi, Director, Rajiv Memorial Education Society's College of Pharmacy, Kalaburagi and Executive Committee Member, Karnataka State Pharmacy Council.

Additional Information on any article is available on request
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